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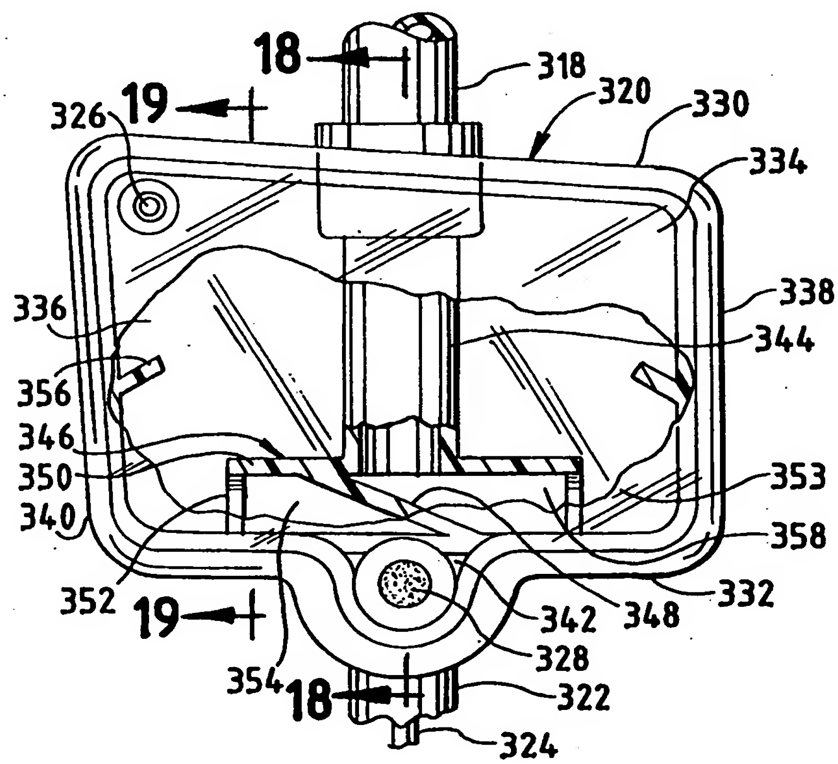
(54) Title: WIDE BUBBLE TRAPS

(57) Abstract

An extracorporeal, flow-through bubble trap chamber (320) has improved bubble separating abilities at high flow rates and generates smaller bubbles. The chamber contains chamber-defining top wall (330), side walls (334, 336) and bottom wall (332) plus blood inlet/outlet ports (322, 344) which extend through top and bottom walls (330, 332) to bring blood into and out of the chamber (320). The chamber (320) preferably has a height that is less than 1.6 times the longest horizontal dimension of the chamber (320). As a result of this, blood flow through the chamber (320) is substantially horizontal. A common flow inlet/outlet tube (350), closed with a central partition (340) is also present.



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WIDE BUBBLE TRAPS

TECHNICAL FIELD

Bubble traps used in blood lines for hemodialysis or the like conventionally comprise a typically rigid or semi-rigid tube in which a blood inlet is provided to convey blood into the top of the chamber, while a blood outlet draws blood from the bottom of the chamber. Bubbles then are given the opportunity to rise to the top of the chamber so that the blood in the bottom of the chamber, which is withdrawn to pass through another portion of the blood set, is relatively free of bubbles, since they migrate to the top of the chamber.

See also Utterberg U.S. Patent No. 5,328,461 and 5,520,640 as other examples of bubble traps for blood lines known to the prior art.

Typically, such bubble traps are higher than they are wide, to provide a deep, vertical chamber for the blood so that bubbles are kept away from the bottom of the chamber, from which the blood is being withdrawn. Typically, the prior art bubble traps have chambers with a vertical height that is more than twice their width. The height of the chambers of the prior art, coupled

with the buoyancy of the incoming bubbles, is intended to counteract the downward bulk fluid flow of blood in the chamber toward the bottom outlet.

The inlets of the prior art blood chambers are variably positioned, the idea being that the blood entering into such inlets, and the bubbles contained in the blood, will initially stay in an upper portion of the chamber so that the bubbles have time to migrate upwardly through a liquid level to a gas space at the top of the chamber. Some inlets are vertically oriented, extending downwardly from the top of the chamber. Because of the height of the chamber, inflowing blood stops moving downwardly before the bubbles contained in it can be caught in the outlet flow. Other inlets of the prior art are vertically oriented in the bottom of the chamber, to propel the inlet blood upwardly toward the chamber top. Other inlets are horizontally oriented in the side of the chamber, so that the inlet flow must horizontally cross the downward flow of the bulk blood in the chamber, moving to an opposite sidewall where it is turned upwardly. This raises the possibility of bubbles being entrained in the downward flow before they are turned upwardly to reach the intended air space.

The bubble trapping principles of the prior art are effective with large, buoyant bubbles, typically having a volume greater than 50 microliters, and at relatively low blood flow rates of less than 300 ml. per minute. Blood chambers for trapping bubbles typically have volumes of about 15-25 ml.. The buoyancy of the bubbles urges them to the surface at a velocity greater than the downward velocity of the bulk flow of the fluid in the bubble trap.

However, such bubble traps are increasingly ineffective as bubbles get smaller, and/or as flow rates increase. Modern dialysis techniques often require blood flow rates exceeding 450 ml. per minute, which raises the risk that bubbles can get through bubble traps of the prior art.

To accommodate such higher flows, the volumes of some designs of prior art bubble traps have been increased. However, this is distinctly undesirable, since that increases the priming volume of the set. It is highly desirable to keep the priming volume of any blood set low, since it is important to minimize the amount of blood removed from a patient at any one time during a blood treatment procedure such as dialysis.

Furthermore, another problem of prior art bubble

traps, particularly those with the upwardly oriented inlets, is that they may require a flow diverter, to prevent blood at high flow rate from bursting through the blood-gas interface in a geyser-like action, which causes foaming of the blood and consequent clotting in the chamber. A typical blood flow diverter comprises an indentation in the wall of the bubble trap, to force the upwardly moving stream of inlet blood into a more horizontal flow, to prevent such geyser-like action. However, the diverter itself is not deemed desirable, and may result in an increased number of bubbles to be driven down toward the bottom outlet and thus to pass out of the bubble trap, contrary to that which was intended.

In accordance with this invention, solutions to the above technical problems are provided, resulting in an improved flow-through bubble trap for blood lines or the like, which is capable of processing blood at high flow rates of 450 ml. per minute and greater, while still retaining a low chamber interior volume.

DESCRIPTION OF THE INVENTION

By this invention, an extracorporeal, flow-

through bubble trap for fluid lines comprises: a chamber-defining wall, a blood inlet, and a blood outlet, each of which extends through the wall to communicate with the interior of the chamber. The blood outlet connects with the chamber interior adjacent the bottom thereof, so that blood is drawn from the bottom of the chamber out of the outlet. The chamber interior preferably has a height that is less than 1.6 times the longest horizontal dimension of the chamber interior, and preferably no more than 1.2 times.

Also, in some embodiments, the blood outlet and blood inlet are typically horizontally separated at their closest points by at least about 8 mm., most preferably at least 10 mm.. As a result of this, blood flow in the bubble trap is substantially horizontal, contrary to the blood chambers of the prior art, which are generally taller than they are wide. Also, since the outlet and inlet may be spaced from each other by at least about 8 mm., there is in that circumstance little or no chance of crossover of inlet blood, with included bubbles, passing immediately from the inlet to the outlet and carrying the bubbles with it. This can be further assured by causing the blood inlet to direct blood flow into the chamber only in a direction or

directions facing away from the blood outlet. The blood outlet may receive blood only from a side facing away from the blood inlet.

It is also preferred for the volume of the chamber interior to be no more than about 25 cc., to contribute to a low priming volume of the set to which the bubble trap belongs.

It is also preferred for the height of the chamber interior to be no more than the longest horizontal dimension of the chamber interior, with the result that the blood flow within the chamber is primarily horizontal.

The bubble trap of this invention may have a blood inlet which comprises a tube that extends into the chamber interior at a position that is spaced at least 4 mm., and preferably at least 5 mm., from any chamber sidewall. An advantage achieved by this is that any foam bridges formed from blood and extending between such a tube and the sidewall are strongly suppressed by having the tube at such a distance from the sidewall, rather than closer as has been customary in the prior art. Such foam bridges formed from swirling, turbulent blood in the bubble trap promote clotting.

Further, the blood inlet tube may preferably

extend between the top and bottom of the chamber, and may be in contact with both the top and the bottom, to provide internal support for the chamber wall. The blood outlet may also comprise a similar (or the same) supporting tube extending between the top and bottom of the chamber. Blood may flow between the chamber and the interior of the inlet and outlet tubes either by a side aperture formed in the respective tubes, or by a recess defined in the inner surface of the chamber wall, which provides space for blood to flow into or out of the end of the inlet and/or outlet tubes around one portion of the annular tube end, while another portion of the annular tube end may press against the bottom wall of the housing.

It is also possible for the flow-through bubble trap of this invention to comprise a chamber-defining wall which defines an interior chamber comprising an upper chamber portion and a lower chamber portion. The upper chamber portion has a greater horizontal area than the lower chamber portion, preferably at least three times greater, with the lower chamber portion being typically positioned toward one side of the upper chamber portion. The upper chamber portion has a height that is less than 1.6 times the longest horizontal

dimension of the upper chamber portion (and preferably 1.2 times). Most preferably, the height of the upper chamber portion is less than the longest horizontal dimension thereof.

A blood outlet is positioned to communicate with a bottom end portion of the lower chamber portion. The blood inlet is positioned to release flowing blood into the upper chamber portion, preferably at a position remote from the lower chamber portion.

It is also preferred for a filter to be carried, typically near the junction of the upper and lower chamber portions, to filter blood flowing between the upper chamber portion and the lower chamber portion. The lower chamber portion may be defined by a cylindrical portion of the chamber-defining wall, so that it can fit into conventional receptacles of air/foam detection apparatus of a type conventionally used in hemodialysis and other blood handling processes. The lower chamber portion may have a horizontal, cross-sectional area that is no more than one third the horizontal, cross-sectional area of the upper chamber portion.

In this embodiment also, it is preferred for the volume of the upper chamber portion to be no more than

about 25 cc.. Also, the blood inlet preferably directs blood flow into the chamber in a direction facing away from the lower chamber portion, so that bubbles have time to rise to an uppermost portion of the chamber before the blood reaches the lower chamber portion. Also, as before, the blood inlet preferably comprises a tube that extends into the chamber interior at a position that is spaced at least 4 mm. and preferably 5 mm from any chamber sidewall, with the tube preferably extending between the top and the bottom of the bubble trap. Also, the inlet tube may have a side aperture or an exposed end to deliver inlet blood preferably in a direction away from the outlet port and substantially spaced below the upper surface of the blood in the upper chamber portion, so that blood at a high flow rate can pass through the upper blood chamber portion without splashing, spattering, or geysering of blood upwardly from the upper blood surface.

The above principles may be used if and as desired in other embodiments where the fluid inlet and fluid outlet to the chamber are arranged in a manner that permits a significant reduction in the size of the chamber. This, in turn, can result in a reduced blood volume in the chamber, which is a valuable improvement,

with the invention also providing other significant improvements and advantages. Such an improved, flow-through bubble trap of this invention for blood lines or the like is capable of processing blood at high flow rates of 450 ml. or greater, while still retaining such a low chamber interior volume.

Such an alternative embodiment of bubble trap may comprise a chamber formed by a chamber-defining wall of one or more connected pieces. A single or multiple component flow inlet/outlet tube (or a pair of coaxial tubes) at least substantially extends through the chamber. The tube (or tubes) can be open at opposed tube ends for connection to other portions of a fluid flow set, for the conveying of blood or the like to and from a patient for hemodialysis or other treatment.

The above flow inlet/outlet tube (or equivalent) defines laterally facing flow inlet and flow outlet ports, each of which are defined to face laterally within the chamber interior. Also, the flow inlet/outlet tube defines a partition or partitions, closing the bore of the tube to substantially prevent direct flow between the flow inlet and flow outlet ports. Thus, a flow circuit is defined in which fluid enters one end of the tube and passes out of the tube

into the chamber interior through the lateral flow inlet port. Then, after circulation through the chamber, the fluid passes through the lateral flow outlet port again into the tube, and continues its journey through the rest of the length of the tube. Short circuiting of fluid flow from this path is substantially prevented by the partition.

As one embodiment, the inlet and outlet ports of the tube are positioned adjacent to a bottom wall portion of the chamber-defining wall. The partition can extend substantially diagonally within the tube, also extending transversely to close the bore. Thus, various portions of the partition peripherally connect with the tube wall in positions which are longitudinally spaced from each other. This permits the flow inlet port and flow outlet port to be positioned at the same longitudinal level along the tube, while being separated from each other by the partition in the tube bore.

As described previously, the chamber interior defined by the chamber-defining wall may have a height that is not substantially greater than the longest horizontal dimension of the chamber interior. In other words, the chamber interior height may preferably be no more than about 1.2 times the longest horizontal

dimension (width) of the chamber interior. Most preferably, the chamber interior has a height that is less than the longest horizontal dimension thereof, so that the flow pattern of fluid within the chamber will have a substantially horizontal overall flow, and the vertical flow component is suppressed when compared with the flow patterns of the vertically extended bubble traps of the prior art.

One end of the flow inlet/outlet tube may be directly connected to a length of roller pump tubing as part of a blood flow set, or to another kind of pump, to provide a compact assembly. A supplemental inlet port may be carried by the chamber-defining wall, communicating with a chamber interior at the end of the bubble trap which is adjacent to the roller pump tubing, shown to be the upper end of the bubble trap in some of the accompanying drawings. The supplemental inlet port preferably extends transversely to the flow inlet/outlet tube, and may connect to a pressure monitor line. Such a transverse pressure monitor line port allows the chamber of this invention to be nested right next to a conventional pump housing of certain commercial hemodialysis machines while the pump tubing is carried in a roller pump assembly of the machine. If the

pressure monitor line port was parallel to the central tube of the chamber, it would interfere with a close, nesting relation with the pump housing of such commercial hemodialysis apparatus.

The flow inlet/outlet tube is preferably spaced by at least about 7 mm. and typically about 9-10 mm. from side wall portions of the chamber-defining wall. The flow inlet/outlet tube may be a central tube extending centrally through a chamber. The flow inlet port preferably faces away from the flow outlet port. The flow inlet and outlet ports may occupy the same longitudinal position along the flow inlet/outlet tube, to provide a swirling inlet and outlet flow through the interior of the chamber that has a substantial horizontal flow component, thus permitting bubbles to rise to the top wall of the chamber and remain there without being swept onward in the flow circuit. This is accomplished with a low volume chamber, having a volume of typically 15 to 30 cc., while still effectively removing bubbles even at high flow rates of at least 450 cc. per minute and the like.

The chamber of this invention can be used in a "pre-pump" or a "post-pump" mode. It is effective for bubble removal with flow in either direction through the

chamber. It may also be used as a venous chamber, as well as an arterial chamber, by the typical application of a filter in the flow outlet of the chamber.

With respect to the previous embodiments, there remains a need for a bubble trap which can be carried by a large variety of different dialysis machines, to greatly reduce the designs of blood sets that a manufacturer must produce and retain in inventory. Such a flow-through bubble trap is provided in the embodiments of this invention as described below, while also exhibiting the many advantages of substantially horizontal flow circulation in the chamber of the bubble trap and the other advantages as described above. Substantial cost savings can be achieved, because the particular design of this invention can be used with a large variety of dialysis machines made by different manufacturers, to greatly reduce the number of designs that must be manufactured in order to keep a complete inventory. Also, the bubble traps of this invention can be directly connected to pump tubing to achieve further economies in the field of reduction of the amount of tubing material necessary to manufacture sets having bubble traps in accordance with this invention. This bubble trap, as are the previously described bubble

traps, may typically be provided as a component of an arterial venous blood set for dialysis or any other blood processing procedure, where blood flows through the bubble trap by first entering and then exiting it, leaving gas bubbles behind. Also the bubble trap can be used as a convenient site for the access of auxiliary branch lines, which may connect to pressure monitors, sources of IV solution, sources of heparin or the like.

By this invention, the bubble trap defines a chamber having top, bottom and sidewalls. The chamber, in turn, defines a substantially flat, lateral side, which can be placed next to any of a variety of dialysis machines with a good operating fit. Examples of such dialysis machines are many of the models sold by Fresenius, Althin, and Baxter International. Thus, since a single set can be used in conjunction with all of these different designs, a great reduction in the number of models and codes for the sets can be achieved.

A first port tube communicates upwardly into the chamber, typically through the bottom wall. A second port tube (which may be a second portion of the first tube if desired) communicates downwardly into the chamber, typically through the top wall. A flow-directing system may preferably be positioned adjacent

to the bottom wall, to direct incoming fluid from one of the port tubes, typically the bottom port tube for "prepump" chamber location or the top port tube for "post-pump" chamber location, into a first, lateral flow direction relative to the direction of flow within the port tubes. From there, the flowing fluid enters into a substantially horizontal fluid flow circulation in the chamber, exhibiting only a relatively minor vertical flow component, contrary to many chambers of the prior art.

The flow directing system also allows fluid flow from the circulating fluid in the chamber to flow into the other of the port tubes in a lateral flow direction that is generally in the same direction as the first lateral flow direction, while preventing direct flow between the first and second port tubes. This feature is found also in previous embodiments disclosed herein.

Preferably, the chamber of this invention has substantially rectangular sidewalls, plus a horizontal width that is at least as great as the height of the chamber and preferably greater than the chamber height, in a manner similar to previous embodiments. This causes the circulating flow within the chamber to be mostly horizontal in nature. The horizontal thickness

or depth of the chamber of this invention is preferably less than both the horizontal width thereof and the height of the chamber. The chamber may have a width on the order of 4 or 5 cm and an internal volume which is preferably no more than about 25 cc, as in previous embodiments.

At least one and typically both of the port tubes are positioned closely adjacent to the flat, lateral side described above, which facilitates fitting of the chamber on a wide variety of dialysis machines. That port tube positioned adjacent to the flat, lateral side may directly connect to a length of roller pump tubing without the need for an intermediate length of flow tubing. This provides an added economy by eliminating such an intermediate length of tubing.

The sidewalls preferably carry at least one inwardly extending, generally horizontal vane to slow the vertical flow component of the substantially horizontal flow circulation. This can further reduce the number of microbubbles of gas which escape through the bubble trap into the outlet flow of blood.

The flow directing system of this invention may comprise an angled wall as a baffle, which is positioned between the first and second port tubes to prevent their

direct flow connection with each other. The baffle system may further comprise horizontal wall portions to direct incoming fluid laterally. Thus blood enters the bubble trap chamber and is directed to one lateral side, preferably along its longest lateral dimension. From there, the blood circulates through essentially the entire lateral width of the major side of the bubble trap, being collected into a passageway from a position adjacent to the opposed lateral side of the chamber. This maximizes the time of horizontal blood flow, which, in turn gives maximum time for microbubbles to rise to the top of the chamber, where they may be trapped.

The chamber of this invention may also carry other ports for connection with branch tubing which may connect to a pressure monitor device, a source of saline solution and/or heparin, and the like. Particularly by this invention, a pressure monitor port may be provided on the respective chamber to communicate with the "highest" portion of the enclosed volume within the chamber irrespectively of whether the chamber is oriented with its back wall in a vertical position, a downwardly facing position, or rotated laterally by approximately 90° while remaining vertical.

In another aspect of this invention, it is

typical in the current art to have an array of access ports carried on blood sets, comprising injection sites and/or branch lines communicating with the set for the administration of medicaments or obtaining blood samples. Prior art injection sites and branch lines appear on main tubes, chamber top caps, chamber walls, or on the IV priming set.

Often, a typical arterial or venous blood tubing set will have three or more access ports. This is due to the variety of modalities of administration and sampling, being influenced by the following factors;

(a) Some medication administrations need to be directly administered into the bloodstream.

(b) Some drugs are more toxic, and must be diluted to lower concentrations with IV fluids before entering the bloodstream.

(c) Other expensive, low volume drugs must be administered directly to the blood, followed by a "saline flush" to assure that all of the drug reaches the blood stream.

(d) Arterial blood samplings need to taken upstream of the flow-through treatment device, typically a hemodialyzer.

(e) Venous samplings need to be taken upstream

of the bubble trap chamber.

(f) Viscous or clot-enhancing administrations must be given on the venous side downstream of the hemodialyzer.

(g) Expensive, low volume drugs must be administered downstream of the venous bubble trap chamber, if said chamber has any stagnant areas that would impede delivery of the drug to the patient.

In the prior art, access ports such as injection sites on the main tubes are suitable for simple drug delivery or blood sampling as the injection sites directly access the blood stream. However, such injection sites are not suitable for diluting drugs or following drug administration with a saline flush. For these modalities, the prior art places an injection site on the IV administration tube away from the blood flow tubing. Of course, this makes such injection sites unsuitable for blood sampling. Furthermore, injection sites on the chamber top caps are suitable for fluid administration, but not for sampling, as the site is adjacent an air space above the blood. Thus, prior art blood tubing sets are equipped with many different kinds of access ports to handle the variety of modalities.

As is well known, however, during most dialyses,

most or all of these ports and tubings are not required. Thus, a substantial portion of the cost of manufacturing blood tubing sets is for access ports that are used very infrequently for occasional or emergency use only. It is therefore highly desirable in today's cost-driven medical environment to reduce the number of access ports on blood tubing sets without reducing the physician's ability to perform necessary administrations or samplings on any of the modalities required.

By this invention, such a reduction can be achieved. This can be accomplished with a flow-through bubble trap having a main chamber and first and sealed port tubes communicating with the main chamber for main fluid flow therethrough. A central manifold is provided which communicates with one of the port tubes adjacent to the chamber. A plurality of auxiliary ports communicate with the central manifold. The auxiliary ports comprise an injection port positioned on the manifold so that an injection needle can penetrate through the injection port and extend into the main fluid flow of the one port tube. Another of the auxiliary ports typically communicates with the length of flexible tubing for connection with a source of intravenous solution.

By such an arrangement, most or all of the various types of medicament administration and blood sampling can be achieved, with the use of only two access ports, although more access ports may be provided if desired.

The bubble trap of many of these inventive chambers may be operated with a substantial air space at the top of the chamber to define a blood level below the top of the chamber. However, due to the enhanced horizontal flow characteristics of the blood in the bubble trap of this invention, and the unique flow and mixing pattern that is provided within the chamber, it becomes possible to operate the bubble trap of this invention with the chamber being substantially filled with blood, so that the surface area of blood exposed to air can be reduced. This has the effect of reducing the tendency of clotting. When chambers of the prior art are filled to the top so as to substantially lack an air space, the blood at the top of such prior art chambers tends to be stagnant during operation, resulting in enhanced clotting, contrary to this invention. Thus, it has been generally necessary in prior art practice to ensure the presence of a substantial air space above the blood level. By this invention, that is no longer

necessary.

It is necessary to take steps to ensure that the blood does not get into the pressure monitor line or any other access line at the top of the bubble trap. This can be accomplished by the placement of a hydrophobic filer at the point where the line communicates with the bubble trap chamber, or by careful filling of the chamber first with saline for priming, and then with blood, keeping track of the various pressures under which the chamber will operate, which of course are generated by varying flow rates through the chamber. However, by this invention, the area of contact between the blood and air can be greatly reduced on a long term basis through the dialysis process. Since the chamber may be substantially completely filled with blood, but for the relatively few bubbles collected during the blood treatment process. Much of the horizontal upper surface of the blood may be in contact with the top chamber wall.

Bubble traps of this invention may, if desired, be of generally oval cross section, either overall, or in the upper chamber portion when a lower chamber portion is present. The horizontal dimensions of such an oval cross section may be approximately 22 by 44 mm.,

with the height of the chamber comprising 30 mm. in one embodiment. This creates a very low priming volume when compared with long, vertical chambers designed for high flows. When a lower chamber portion is present, it also may preferably have a height of about 30 mm.

DESCRIPTION OF THE DRAWINGS

In the drawings, Fig. 1 is a perspective view of one embodiment of the chamber of this invention;

Fig. 2 is a plan view of the chamber of Fig. 1;

Fig. 3 is a vertical section of the chamber of Figs. 2, taken along line 3-3 of Fig. 2;

Fig. 4 is a vertical sectional view taken along line 4-4 of Fig. 2;

Fig. 5 is a plan view of another embodiment of bubble trap in accordance with this invention;

Fig. 6 is a vertical sectional view taken along line 6-6 of Fig. 5;

Figs. 7, 8, and 9 are vertical sectional views of other embodiments of bubble trap in accordance with this invention;

Fig. 10 is a top plan view of the chamber of this invention;

Fig. 11 is an elevational view taken partly in section along line 11-11 of Fig. 10, also showing connection of the chamber to other components of an otherwise conventional hemodialysis blood flow set;

Fig. 12 is a sectional view taken along line 12-12 of Fig. 10;

Fig. 13 is a sectional view taken along line 13-13 of Fig. 10;

Fig. 14 is a sectional view taken along line 14-14 of Fig. 10;

Fig. 15 is a bottom plan view of the bubble trap of this invention;

Fig. 16 is a fragmentary perspective view showing another embodiment of an arterial blood set of this invention carried on a roller pump of a conventional hemodialysis machine;

Fig. 17 is an enlarged, elevational view of the chamber of Fig. 16 with portions broken away;

Fig. 18 is a sectional view taken along line 18-18 of Fig. 17;

Fig. 19 is a sectional view taken along line 19-19 of Fig. 17;

Fig. 20 is a perspective view of the arterial blood set of Fig. 16, inserted into a different roller pump which is substantially horizontally positioned;

Fig. 21 is an elevational view of the arrangement of Fig. 20; and

Fig. 22 is a perspective view of the blood set of Fig. 16 installed in another roller pump set which is rotated about 90° from the roller pump of Fig. 16, so

that the roller pump tubing is inserted laterally into the roller pump.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to Figs. 1 through 4, a bubble trap 10 is shown, being suitable for use to replace the bubble traps of conventional arterial or venous hemodialysis sets, as well as other blood handling sets, or any conduits where a small, highly effective degassing chamber is desired. Bubble trap 10 is of the flow-through type, since the blood flows into chamber 11 of the bubble trap through inlet port 12, and out again through outlet port 20. Chamber 11 is surrounded by wall 13 on all sides thereof.

Chamber 11 comprises an upper chamber portion 14 and a lower chamber portion 16, lower chamber portion 16 being defined by a cylindrical, transparent portion 18 of wall 13, proportioned to fit into a conventional air/foam detector. Typically all of wall 13 is transparent. Upper wall 24 may comprise a separately molded lid, if desired, which is peripherally bonded to chamber 11 to become part of wall 13.

Blood flow outlet 20 is then defined at the

bottom of lower chamber portion 16. Conventional set tubing 13, 15 respectively connects to inlet and outlet 12, 20.

Upper chamber portion 14 is dimensioned to have a height 22 that is less than the maximum width 23 of upper chamber portion 14.

Lower chamber portion 16 can be seen to be positioned adjacent to one side of upper chamber portion 14 at a position horizontally remote, typically by at least 8 mm. from the nearest portion of blood inlet 12.

Blood inlet 12 communicates with an interior tube 26 that extends through upper wall portion 24 of the bubble trap and extends through chamber 14 into contact with or nearly adjacent with lower wall portion 28. Tube 26 defines a cut away side portion 30 of its wall, facing away from lower chamber portion 16, so that inflowing blood as illustrated by arrow 32 enters through inlet 12 and tube 26 in a vertical flow pattern, and is turned at the end of tube 26 by wall portion 28 into a horizontal flow through side aperture 30, away from second chamber portion 16. Tube 26 is also spaced at least 5 mm. from the nearest sidewall portion 34 of bubble trap 10, to avoid the undesirable creation of a bridge of blood/foam between tube 26 and wall 34 or

vertical annular member 35, which forms a lid or cover member with upper wall portion 24 that closes the chamber.

An air space 36 above the blood level 38 is shown as one normal condition for operative blood flow through the bubble trap. However, as previously described, it is also possible to operate this bubble trap with the blood level substantially in contact with the undersurface of upper wall portion 24, to minimize the area of the blood-air interface. By the particular design of bubble trap disclosed in this invention, a distinct, generally horizontal, swirling flow pattern for the blood can be provided, where blood next to the undersurface of upper wall portion 24 is not stagnant, but participates in a good flow, to suppress blood clotting. Collected air bubbles may be periodically removed through an access port 46 (Fig. 2).

Tubing connector 40 is conventionally provided to permit access to a tube that leads to a pressure sensor in conventional manner, or an additive tube for the conventional addition of saline solution or desired medications.

The bubble trap also defines a basket-type filter 44 which is positioned adjacent to the junction between

the upper and lower chamber portions 14, 16, leaving open the majority of lower chamber portion 16. Thus, the cylindrical wall portion 18 of the lower chamber portion 16 may be inserted into a conventional air-foam detector, with filter 44 being out of the way so that air and foam can be detected underneath it in the conventional manner during a dialysis procedure. Annular securance ring 45 of filter 44 may be conventionally secured in the position shown. The shorter, lower chamber that results from this "mid-chamber" filter has reduced priming volume than a normal vertical chamber with the filter at the bottom and with the ultrasound air/foam sensing signal passing above the filter.

Because of the primarily horizontal flow of blood in upper chamber 14, air bubbles in the blood are given more opportunity to migrate upwardly to the top of the chamber than in other designs of bubble trap, where the bubbles have to rise against a downward flowing current of blood. It can be seen that there is no major downward flow of the blood in chamber 14 in the left half of the chamber (Fig. 3), giving the bubbles extra opportunity to rise to air space 36 despite the fact that the volume of upper chamber 14 is preferably less

than 25 cc., (and the volume of lower chamber 16 is correspondingly low). It is possible to run high flow rates of blood, of 450 ml. per minute and greater, while still reliably and effectively separating out essentially all bubbles, so that the outflow of blood through outlet port 20 is substantially bubble free.

Referring to Fig. 3, the right hand wall portion 26a of tube 26 is horizontally separated by more than 8 mm. from the left hand wall portion 18a, which surrounds lower chamber 16.

Thus, a uniquely effective, high flow capacity bubble trap is provided, being typically used in extracorporeal blood sets, but also suitable for other desirable uses of fluid handling.

Referring to Figs. 5 and 6, another embodiment of a bubble trap is disclosed, comprising a chamber 50 which is defined on all sides by a chamber-defining wall 52, and has a volume of less than 25 cc.. Wall 52 may, in turn, be defined by a cup 54 which is closed with a cap 56. Cap 56, in turn, is a molded structure that also integrally defines inlet port 58, outlet port 60, and internal tubes 62, 64 that serve to convey the blood into the chamber interior. Both tubes 62, 64 are proportioned so that their lower ends engage or are at

least adjacent the inner wall of chamber bottom wall portion 66. Each of flow tubes 62, 64 have enlarged inlet port openings to respectively receive flexible blood tubing or pump segment tubing sections 68, 70 as part of an extracorporeal blood set, which may otherwise be of conventional design. The above is similar in part to the previous embodiment.

Tube 62 defines a side opening 72 comprising typically one-half or less of the circumference of tube 62 and facing away from tube 64. Thus, blood flow from flexible tubing 68 enters inlet 58, and passes downwardly through tube 62 until it is turned into horizontal flow by bottom wall portion 66, to flow out of aperture 72 in a generally horizontal flow pattern as indicated by arrow 74. Because chamber 50, defined by wall 52, is wider in at least one horizontal dimension than it is in the vertical dimension, the flow of blood is primarily horizontal. This makes it possible for bubbles to rise to air space 76 above blood level 78, without encountering a net downward flow of the blood in the left hand majority of chamber 50.

The bottom wall 66 defined by cup 54 further carries an internal recess 80. Tube 64 has a slanted end so that only a portion of the circumference of the

end 82 of tube 64 is actually in contact with bottom wall portion 66. Typically, this portion of wall-contacting tube end may comprise less than one-half of the circumference of tube 64. Thus, outflowing blood passes through recess 80, around the end of tube 64 and into the bore thereof, to exit through outlet port 60 into flexible blood tubing 70, and on through the conventional extracorporeal blood set to which the bubble trap is attached.

Cap 56 may also carry one or more access ports 63, which may be a needle injection site, or may connect to tubing which carries a needle injection site, or which may connect to saline solution, additional medication, or the like. Port 65 (Fig. 5) may connect to a pressure monitor line of conventional design and purpose.

Here also, it is possible to raise blood level 78 into substantial contact with the undersurface of cap 56, to minimize the gas/blood interface area, which has the desirable characteristic of suppressing clotting of the blood. This can be accomplished with suppressed clotting at high flow rates, and even at low flow rates of 150 ml. per minute in the bubble trap of this invention because of the unique, swirling flow

characteristics that prevent a stagnant area of blood from forming in the area immediately underneath cap 56. Also, at high flow rates in excess of 450 ml., the bubble trap of Figs. 5 and 6 operates effectively to remove bubbles, even though the volume of chamber 50 may be on the order of 20 ml.

Referring to Fig. 7, another embodiment of bubble trap is shown, similar to the embodiment of Figs. 5 and 6 except as otherwise described herein. Chamber 50a is defined by sidewall 52a, and has preferably less than a 25 cc. volume. Chamber 50a comprises an inlet port 58a which passes through bottom wall 66a of the chamber, being defined by fitting 84.

Fitting 84 also defines another pair of inlet ports 86 (one behind the other) which may connect with outer inlet tubing that, in turn, connect a source of saline solution, heparin, or the like. The chamber of Fig. 7 also defines an outlet port 60a extending through bottom wall 66a. The respective inlet and outlet ports are connected to flexible tubing 68a, 70a for conventional incorporation into an arterial or a venous set.

In this embodiment, the maximum width of chamber 50a remains greater than the height of the chamber. The

horizontal cross section of the chamber of Fig. 7 is the same as that shown in Fig. 5. Accordingly, while blood flow can enter through the chamber 50a bottom vertically upwardly, the flow within the chamber remains primarily horizontal. Bubbles are expelled upwardly from inlet 58a to air space 76a in a manner similar to the previous embodiment. Then, the primarily horizontal flow of blood to the bottom outlet 60a gives residual air bubbles the opportunity to rise toward air space 76a so that bubble-free fluid only passes through outlet port 60a.

Referring to the bubble trap of Fig. 8, chamber 50b is defined by a sidewall 52b, which is of similar design to sidewall 52 of Fig. 6, having a lid or cover 56b as in the previous embodiments.

Blood entry port 58b enters through the top wall 56b in this embodiment, having a tube 62b that extends the height of chamber 50b, and has a side aperture 72b in the manner of the Fig. 6 embodiment, to place blood well under the surface 78b of blood in the chamber for the avoidance of geysering and spattering.

Blood outlet 60b is positioned to extend directly through bottom wall 66b as in the embodiment of Fig. 7.

Thus, blood may enter chamber 50b in the manner

of the Fig. 6 embodiment, but it exits chamber 50b in the manner of the Fig. 7 embodiment. Because of the proportions of chamber 50b, longer in its longest horizontal dimension than it is high, the excellent bubble removal characteristics of this invention are achieved. Fig. 5 represents a horizontal cross section of Fig. 8 as well as that of the previous embodiments of Figs. 6 and 7.

This chamber also has a preferable volume of less than 25 cc. Also, bottom port 67 can connect with tubing that communicates with a heparin source, for example, or saline solution.

Each of the chambers of Figs. 6-9 can operate with the flow through them being in the opposite direction; i.e., outlet ports become the inlet ports, while the inlet ports become the outlet ports. In either case, effective removal of bubbles takes place from fluids.

Referring to the bubble trap of Fig. 9, chamber 50c is defined by a sidewall 52c, which is of similar design to sidewall 52 of Fig. 6, having a lid or cover 56c as in previous embodiments.

Blood entry port 58c enters through the bottom wall 66c in this embodiment. A blood entry tube 62c is

present as in previous embodiments, defining an internal entry side port 72c at or near the bottom of chamber 50c, as in previous embodiments. However, as a difference from previous embodiments, tube 62c has an internal wall 81, positioned so that all of the entering blood goes into chamber 50c through side aperture 72c. Tube 62c is surrounded by chamber 50c in a manner similar to tube 62, surrounded by chamber 50, in Figs. 5-6.

Thus, as in previous embodiments, the entering blood passes primarily in a horizontal direction as shown by arrow 82, which facilitates the upward rise of bubbles into an air space 76c or, if no air space is used, to the undersurface of top wall 56c.

Outlet tube 64c is also provided, having a bevelled end 84, a minor portion of which rests against the bottom wall 86 of recess 80c so that a space 88 is provided for blood flow from chamber 50c and recess 80c into outlet tube 64c, as shown by arrow 90. Outlet tube 64c connects to flexible tube 70c, which preferably may be a peristaltic pumping segment.

Thus, it can be seen that bubble free blood passes through outlet tube 64c and into flexible set tubing 70c in a manner similar to that of the previous

embodiments.

Access port 63c, similar to port 63 of Fig. 6, can also be provided for similar purposes.

Referring to Figs. 10 through 15, another embodiment of a flow through bubble trap 110 is disclosed, being typically used as part of arterial or venous blood sets for the circulation of blood between a patient and a blood treatment device, for example as in hemodialysis. Such blood sets of the prior art are manufactured and sold by the Medisystems Corporation of Seattle, Washington, among others. As shown in Fig. 11, bubble trap 110 comprises a chamber defining wall 112 made of a cylindrical cup-shaped member 114 closed at one end 115, and closed at the other end with a cap 116, which is peripherally sealed to cup 114 about flange 117.

The bubble trap with its chamber defining wall 114 comprises a part of a blood handling set of any desired design, comprising flow tubing 118, roller pump tubing 120 of larger diameter than flow tubing 118, and various branch tubings 122, 124, 126, each of which communicates with the chamber interior 128. Tubing 122 may connect with a pressure monitor of conventional design. Tubing 124 may comprise a blood or other fluid

access line. Tubing 126 may connect to a source of intravenous solution such as 0.9% saline or the like, to permit rapid and convenient administration of saline solution if and when needed.

Chamber wall 112 surrounds a two-component flow inlet/outlet tube 130, which extends completely through chamber 112 except for a possible gap at area 133, and is open at its opposed ends 132, 134. A first tube component comprises tube 130 which is attached to, and preferably comolded with, cap 116. A second, coaxial tube component comprises tube 130 which is integral with bottom wall 115 of cup-shaped member 114, and also may be comolded with that piece. When cap 116 is sealed to cup member 114, first tube 130 is positioned as shown in Figs. 11-13. A small gap may be present between lower end 133 of first tube component 130a and bottom wall 115 so that the parts may be molded with relatively low tolerance and reliably sealed together without first tube component 130a being accidentally made too long, which would interfere with the sealing of cap 116 and cup member 114. A small amount of fluid leakage between the end 133 and bottom wall 115 is generally of little consequence.

End 132 comprises an aperture for conventional,

sealed connection with flow tube 118 and tube component 130b. Tube end 134 may be of a different size to similarly seal with pump tubing 120.

Flow between set tubing 118 and roller pump tubing 120 does not proceed directly through the length of flow inlet/outlet tube 130, as is particularly illustrated by Fig. 12. The bore 131 of tube component 130a is closed by a diagonal partition 136, which extends diagonally along the length of the interior of tube component 130a and essentially separates and diverts tube inlet flow from outlet flow. A flow inlet port 138 is defined in the wall of tube component 130a within the chamber interior 128. A flow outlet port 140 is also defined in the wall of tube component 130 within chamber interior 128, with partition 136 essentially closing and separating the bore of tube 130 between inlet and outlet ports 138, 140. By the arrangement shown in Fig. 12, it is possible for ports 138, 140 to be at the same longitudinal position along the length of tube 130, but facing away from each other, while being separated by partition 136.

Thus, as indicated by the flow arrows 142, which illustrate a "prepump" arterial chamber installation, blood or other fluid can enter tube 130 at end 132 from

set tubing 118. The flow passes out of flow inlet port 138 into chamber interior 128, circulating in the chamber interior 128 in a substantially horizontal, circumferential flow pattern around tube 130 until it reaches flow outlet port 140. Then, the flow reenters tube 130 through port 140 again on the other side of partition 136, and passes upwardly as shown by flow arrows 142 to exit the tube 130 from end 134 into the pump tubing 120. As this takes place, bubbles in the fluid can rise and be trapped against the lower surface of cap 116, and in bubble accumulating space 117, when tubing 130 occupies a substantially vertical position as shown, so that the bubbles are trapped and do not pass onwardly through flow outlet port 140.

It is to be understood that the bubble trap of this invention can operate in the opposite direction if desired, with the flow inlet coming through tube end 134 and the flow outlet exiting through tube end 132. In this case, the function of the flow ports 138, 140 is reversed, and the flow pattern is reversed, which can effectively take place in this design of chamber without a loss of bubble trapping capability. Tube 120 may also be a non-pump tube if desired, such as when chamber 110 is used as a venous chamber.

It can be seen that the auxiliary lines 122, 124, 126 are respectively connected to molded ports 121, 123, 125 in conventional, sealed manner to provide connection to chamber 112. Port 121 connects horizontally to the chamber interior 128 through aperture 146 (Fig. 15), permitting chamber 210 to fit snugly next to the roller pump housing of a hemodialyzer machine. Port 125 connects to a common channel 148 with port 123, which, in turn, connects to the interior of tube 130 adjacent to the end 132 of tube 130. Thus, communication is provided between all of the connecting lines and chamber interior 128.

The chamber interior 128 may have height of about 18-32 mm. (measured to the bottom of top wall 116) and an outer diameter of about 26-40 mm., to preferably give it a blood volume, including the volume of tube 130, of about 15-30 cc. Thus, a significant size reduction is achieved while the chamber still is highly effective at removing bubbles from blood at high flow rates.

Referring to Figs. 16-22, a conventional dialysis machine 310 is shown having a face plate 312 through which a roller pump 314 projects. An arterial set for hemodialysis 316 is provided, being of generally conventional construction except as otherwise indicated

herein. Arterial set 316 carries conventional roller pump tubing 318 fitted into the roller pump 314 in a conventional manner.

Roller pump tubing 318 connects with a flow-through bubble trap chamber 320 in accordance with this invention. Bubble trap chamber 320, in turn, has several ports that respectively connect with the main flow tubing 322 of arterial set 316 and branch connection lines 324, 326, which may be conventional in design per se, and are provided for the purpose of connection with a pressure monitor, a source of IV solution, a source of heparin, or the like. Chamber 320 can also carry an aperture 328 which is filled with an elastomer-type resealable injection site.

Branch connection line 326 and the corresponding port communicates with chamber 320 and serves as the pressure monitor port and line. The line and port 326 communicate with the "highest" portion of the volume enclosed in chamber 320 when back wall 336 is in the vertical position as shown, but also if back wall 336 is in a substantially horizontal position as in Fig. 20, or if chamber 320 is rotated so that sidewall 338 is the lowest wall in the position of use of chamber 320, as in Fig. 22.

If the roller tubing 318 rotates clockwise in direction, chamber 320 is in a "pre-pump" location, and blood flows from main flow tubing 322 to roller tubing 318. Pressures in the chamber are then typically negative, and port 324 is typically a source for IV solution administration. If roller tube 318 rotates counterclockwise, chamber 320 is in a post-pump location. Flows proceed from roller tubing 318 to main flow tubing 322. Pressures then are typically positive in chamber 320.

Fig. 17 shows chamber 320 to be substantially, but not exactly, rectangular in shape, having a top wall 330, a bottom wall 332, opposed major sidewalls 334, 336 and opposed minor sidewalls 338, 340. It can be seen that chamber 320 is wider than it is tall, so that the flow circulation through the chamber is substantially horizontal, with only a relatively minor vertical flow component.

Chamber 320 defines a first port 342 that communicates upwardly into the chamber. Chamber 320 also defines a second port 344 that communicates downwardly into the chamber, passing through upper wall 330, as first port 342 extends through lower wall 332.

A flow-directing baffle system 346 is provided

adjacent to bottom wall 332, to direct incoming fluid from one of the port tubes 342, 344 into a first lateral flow direction. Specifically, the baffle system 346 comprises an angled wall 348 positioned between the top of first port tube 342 and the bottom of second port tube 344. Baffle system 346 also comprises horizontal wall portions 350, through which second port 344 passes, and which portions 350 connect with angled wall 348. The sides or ends 352, 353 under horizontal wall 350 are open to the interior of chamber 320, while walls 348, 350 extend to join (as a part of or abutting against) major sidewalls 334, 336. Sidewall 336 may comprise the flat back wall previously discussed, which permits installation of the chamber of this invention into a large variety of hemodialysis machines.

Flow-through chamber 320 can pass flow in either direction with substantially similar results. If the flow is upward, with first port tube 342 connected to and receiving blood from set tube 322, the blood rises upwardly into the first space 354, defined by the lower surface of angled wall 348 and a portion of horizontal wall 350, to flow to the left through open side or end 352 in a horizontal manner, and thus to enter into circulating flow within chamber 320. The upward motion

of such blood in circulating flow is restricted but not eliminated by the presence of horizontal vane 356, which is carried by minor sidewall 340.

Blood is then withdrawn from chamber 320 through a passageway 358 defined by the upper surface of angled wall 348 and a right hand portion of horizontal wall 350, blood being drawn in from the open side or end 353 from the circulating flow of blood within the chamber, to be drawn upwardly through second port tube 344, and from there into roller pump tubing 318, which is conventionally attached to second port tubing 344. Second horizontal vane 356a is provided to further restrict but not eliminate the vertical flow component in the chamber.

If flow is in the other direction, initially from roller pump tubing 318 into second port tube 344, the pattern of flow is in the opposite direction, with similar bubble removing characteristics, with the flowing blood passing downwardly through first port tube and out along set tubing 322.

Since the major portion of the flow component of this chamber is preferably horizontal rather than vertical, improvements are achieved in the removal of bubbles from blood, including microbubbles. Such

bubbles and microbubbles migrate to the top of the chamber where they reside until removed, for example by removal through the tube 326 and the aperture of the chamber which retains such tube.

It can be seen from Fig. 18 that roller pump tubing 318 and second port tube 344 are positioned along rear sidewall 336 of the chamber. This facilitates the fitting of sets carrying the chamber of this invention with a larger number of commercially available hemodialysis machines, so that the number of different designs and codes of respective arterial (and venous) sets using the chamber of this invention may be reduced.

Though terms such as "up", "down", "height" and "width" have been used to define the chamber in the orientation of Figs. 1-4, it is a feature of this invention that it can be successfully operated in other orientations as well. For example, see Fig. 20, in which the chamber works with a conventional blood pump 314a that is essentially horizontal rather than vertical. In this orientation, the back wall 336 of Figs. 17-19 becomes bottom wall 336 of Fig. 21. The flows in chamber 320a of Figs 20-21 are still primarily horizontal rather than vertical, so that the chamber functions as described above for the original

orientation.

Thus, this chamber may be used on dialysis machines in which the roller pump is substantially horizontal.

Some other machines have blood pumps with a vertical orientation, but with the pump's opening turned to the side. In Fig. 22, pump 314b shows this orientation. Chamber 320b here is positioned on its side such that the sidewall 338 becomes the bottom wall 338 of Fig. 22. Monitor tubing and port 326 of Fig. 17 remains the monitor tubing 326a, 326b in the same port of the Fig. 20 and Fig. 22 embodiments. The monitor tubing in port 326 still communicates with the highest point in the chamber, and thus is unlikely to pick up blood from the chamber. However, air can be vented through this port and tubing 326 as desired.

The chamber of this invention defines a central manifold passage 360, which serves as a plenum for the mutual connection of injection site port 328, branch or auxiliary tubing 324 (and the port to which it is attached), and first port tube 342, so that they all can connect with space 354. Space 354, in turn connects with the main portion of the chamber interior. Tubing 324 may preferably comprise a full priming set of

conventional design.

Central manifold 360 and its connecting arrangement with injection site 328, line and port 324 (typically used for priming), and first port tube 342 which connects with line 322 are arranged to permit all of the desired arterial administrations and samplings as described below. Specifically, manifold 360 is substantially cylindrical with injection site 328 positioned at one end and positioned perpendicular to the main flow of fluid through port tube 322 and its connecting port 342.

Thus, a regular medicament may be infused by cannula through injection site 328 directly into the blood stream, with the cannula entering central manifold 360 into main port 342 so as to be in the direct stream of flow. Such a cannula may be a sharp cannula or a blunt cannula in the manner of the blunt cannula described in Utterberg Patent No. 5,071,413. Injection site 328 may carry a solid or a slit elastomer partition 328a, or it may comprise a branch line with a female luer connector, or a stop cock, or any such suitable flow control connection.

A toxic medicament may be infused by a cannula through injection site 328, while simultaneously

infusing saline via tubing and port 324. The central manifold 360 allows a dilution space for mixing of the drug with the saline and then the blood.

An expensive or low volume drug may be infused by cannula through injection site 328, followed by a saline flush via saline port 324, which clears any residue drug from central manifold 360 and passes it into the main flow of port 342.

Blood may be sampled by passing a cannula through injection site 328 and central manifold 360 to extend directly into the main flow path for blood in port 342.

If desired, medicament may be administered through solution line 324.

By the above means, the number of access ports required on a blood conveying set can be reduced to two ports, which can serve every needed function of medicament administration and sampling that can be achieved from the particular location.

Branch line at 326 may then connect to a pressure sensing monitor.

Most of chamber 320 can be molded in a cup-shaped configuration as shown in Fig. 19. Then, separately molded front wall 334 may be attached and sealed at the molded sealing groove 362, which engages with each of

the walls to provide a hermetically sealed chamber except at its various access ports.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

THAT WHICH IS CLAIMED:

1. An extracorporeal, flow-through bubble trap for fluid flow lines, which comprises: a chamber-defining wall; a flow inlet and a flow outlet, each extending through said wall to communicate with the interior of said chamber, said flow outlet connecting with said chamber interior adjacent the bottom thereof, said chamber interior having a height that is less than 1.6 times the longest horizontal dimension of said chamber interior, whereby fluid flow in the bubble trap chamber is substantially horizontal, said flow inlet directing fluid flow into said chamber in a direction away from said outlet.

2. The bubble trap of Claim 1 in which the volume of said chamber interior is no more than about 25 cc..

3. The bubble trap of Claims 1-2 in which the height of the chamber interior is no more than the longest horizontal dimension of said chamber interior, whereby said fluid flow in the chamber is primarily horizontal.

4. The bubble trap of Claims 1-3 in which the fluid outlet and inlet are horizontally separated at their closest points by at least about 8 mm..

5. The bubble trap of Claims 1-4 in which said fluid inlet comprises a tube that extends into said chamber interior at a position that is spaced at least 4 mm. from any chamber side wall.

6. The bubble trap of Claims 1-5 in which said fluid inlet and said fluid outlet each comprise tubes that extend from the top to the bottom of said chamber.

7. The bubble trap of Claims 1-6 in which said fluid inlet comprises a tube that communicates with the interior of said chamber at a position adjacent the bottom of said chamber interior.

8. An extracorporeal, flow-through bubble trap for bloodlines, which comprises: a chamber-defining wall which defines an interior comprising an upper chamber portion and a lower chamber portion, said upper chamber portion having a greater horizontal area than said lower chamber portion, said upper chamber portion

having a height that is less than 1.6 times the longest horizontal dimension of said upper chamber portion, said lower chamber portion being positioned toward one side of said upper chamber portion; a blood outlet positioned to communicate with a bottom end portion of said lower chamber portion; and a blood inlet positioned to release flowing blood into said upper chamber portion.

9. The bubble trap of Claim 8 in which said blood inlet releases said flowing blood in a direction horizontally away from said blood outlet.

10. The bubble trap of Claims 8-9 in which a filter is carried near the junction of the upper and lower chamber portions, to filter blood flowing between said upper chamber portion and said lower chamber portion.

11. The bubble trap of Claims 8-10 in which the volume of said upper chamber portion is no more than about 25 cc.

12. The bubble trap of Claims 8-11 in which said lower chamber portion has a horizontal cross-sectional

area that is no more than one-third of the horizontal cross-sectional area of the upper chamber portion.

13. The extracorporeal, flow-through bubble trap of Claims 8-12 in which said upper chamber portion has a height which is no more than the longest horizontal dimension of said upper chamber portion.

14. The bubble trap of Claims 8-13 in which said lower chamber portion defines a cylindrical, outer, transparent wall capable of fitting into an air/foam detector.

15. The method of passing blood through an extracorporeal, flow-through bubble trap for blood lines, which bubble trap comprises a chamber-defining wall, a blood inlet, and a blood outlet, each extending through the wall to communicate with the interior of the chamber, in which the blood outlet communicates with the chamber interior adjacent the bottom thereof, and the chamber interior has a top wall and a height that is less than 1.6 times the longest horizontal dimension of the chamber interior so that the blood flow in the bubble trap chamber is substantially horizontal, said

method comprising: filling said chamber with blood to cause a substantial portion of the top wall of said chamber to be in continuous contact with said blood, and passing blood into said blood inlet and out of said blood outlet to cause bubbles to be removed from said blood and to collect directly underneath said top wall.

16. The method of Claim 15 in which the flow rate of blood through said chamber is at least about 450 ml. per minute.

17. The method of Claims 15-16 in which the volume of said chamber is no more than about 25 cc..

18. The method of Claims 15-17 in which the horizontal cross section of said chamber is substantially oval, and said blood outlet draws blood from said chamber at a location adjacent the bottom thereof at a position opposed along the major axis of said cross section to the position of said blood inlet.

19. The method of Claims 15-18 in which the height of said chamber interior is no more than the longest horizontal dimension of said chamber interior.

20. An extracorporeal, flow-through bubble trap for fluid flow lines, which comprises: a chamber-defining wall; a flow inlet and a flow outlet each extending through said wall to communicate with the interior of said chamber, at least said flow outlet communicating with the chamber interior adjacent the bottom thereof, said flow inlet directing fluid flow into said chamber exclusively in directions facing horizontally away from said flow outlet.

21. The bubble trap of Claim 20 in which the volume of said chamber interior is no more than about 25 cc..

22. The bubble trap of Claims 20-21 in which said fluid inlet comprises a tube that extends into said chamber interior at a position that is spaced at least 4 mm. from any chamber sidewall.

23. A flow-through bubble trap for fluid flow lines, which comprises:

a chamber-defining wall;

a flow inlet/outlet tube at least substantially extending through said chamber and open at opposed tube

ends, said tube defining: a laterally facing flow inlet port within the chamber interior, an opposed laterally facing flow outlet port within the chamber interior; and a partition closing the bore of said tube between said flow inlet and outlet ports.

24. The bubble trap of Claim 23 in which said inlet and outlet ports are positioned adjacent to a bottom wall portion of said chamber-defining wall.

25. The bubble trap of Claims 23-24 in which said partition extends diagonally within said tube.

26. The bubble trap of Claims 23-25 in which said chamber-defining wall is substantially circular in cross section.

27. The bubble trap of Claims 23-26 in which the chamber interior has a height that is substantially not greater than the longest horizontal dimension of said chamber interior.

28. The bubble trap of Claims 23-27 in which said flow inlet/outlet tube comprises a pair of

separate, substantially coaxial tube sections.

29. The bubble trap of Claims 23-28 in which one end of said flow inlet/outlet tube is directly connected to a length of roller pump tubing.

30. The bubble trap of Claim 23-29 in which said chamber-defining wall carries a supplemental inlet port communicating with the chamber interior at an end of said bubble trap adjacent to said roller pump tubing, said supplemental inlet port extending transversely to said flow inlet/outlet tube.

31. The bubble trap of Claim 30 in which said flow inlet/outlet tube is spaced by at least 7 mm. from side wall portions of said chamber-defining wall.

32. The bubble trap of Claims 23-31 in which said chamber-defining wall comprises a cup-shaped chamber member having a bottom wall, said cup-shaped chamber member being closed by a peripherally sealed lid member at an end opposed to said bottom wall;

33. A flow-through bubble trap for fluid flow

lines, which comprises:

a chamber having top, bottom, and side walls, said chamber defining a substantially flat, lateral side;

a first port tube communicating upwardly into said chamber;

a second port tube communicating downwardly into said chamber;

a flow-directing system positioned to direct incoming fluid from one of said port tubes into a first lateral flow direction, and then to allow substantially horizontal fluid flow circulation in said chamber, said flow-directing system also allowing fluid flow from circulating fluid in said chamber into the other of said port tubes in a lateral flow direction that is generally the same as said first lateral flow direction, while preventing direct flow between said first and second port tubes.

34. The bubble trap of Claim 33 in which said chamber has substantially rectangular sidewalls, and a horizontal width that is at least as great as the height of said chamber.

35. The bubble trap of Claims 32-34 in which said chamber has a horizontal thickness that is less than each of said horizontal width and said height.

36. The bubble trap of Claims 32-35 in which at least one of said port tubes is positioned adjacent to said flat, lateral side, and directly connects to a length of roller pump tubing.

37. The bubble trap of Claim 32-36 in which said sidewalls carry at least one inwardly extending horizontal vane to slow the vertical flow component of said substantially horizontal flow circulation.

38. The bubble trap of Claims 32-37 in which said flow directing system comprises an angled wall positioned between said first and second port tubes.

39. The bubble trap of Claims 32-38 in which said flow directing system further comprises horizontal wall portions to direct incoming fluid from one of said port tubes to one lateral side of said chamber, and to define a horizontal passageway extending from an opposed lateral side of said chamber to convey fluid from said

chamber to the other of said port tubes.

40. The bubble trap of Claims 32-39 in which said second port tube extends downwardly through said chamber to a position at least near said flow-directing system.

41. The bubble trap of Claims 32-40, which comprises:

a central manifold that communicates with one of said port tubes adjacent to said chamber;

a plurality of auxiliary ports that communicate with said central manifold, said auxiliary ports comprising an injection port positioned on said manifold so that an injection cannula can penetrate through said injection port and extend into main fluid flow of the one port tube, another of said auxiliary ports communicating with a length of flexible tubing for connection with a source of intravenous solution.

42. The bubble trap of Claims 32-41 in which said central manifold is of straight, tubular shape, said injection port being positioned at one end of said tubular shape of the manifold and the other end of said

manifold tubular shape communicating with one of said port tubes in transverse relation thereto, another auxiliary port communicating with said manifold in transverse relation thereto.

43. The bubble trap of Claims 32-42 in which said first port tube communicates upwardly into said chamber and said second port tube communicates downwardly into said chamber, said chamber further defining a flow-directing system positioned to direct incoming fluid from one of said port tubes into a first lateral flow direction, and then to allow substantially horizontal fluid flow circulation in said chamber, said flow-directing system also allowing fluid flow from circulating fluid in said chamber into the other of said port tubes in a lateral flow direction, while preventing direct flow between said first and second port tubes.

44. A chamber carried by a flow set for blood, said chamber comprising: a central manifold that communicates with a port tube communicating with said chamber; a plurality of auxiliary ports that communicate with said central manifold, said auxiliary ports comprising an injection port positioned on said manifold

so that an injection cannula can penetrate through said injection port and extend into main fluid flow with the one port tube, another of the auxiliary ports communicating with a length of flexible tubing for connection with a source of intravenous solution.

45. The chamber of Claim 44 in which said central manifold is of straight, tubular shape, said injection port being positioned at one end of said tubular shape of the manifold and the other end of said manifold tubular shape communicating with said port tube in transverse relation thereto, another auxiliary port communicating with said manifold in transverse relation thereto.

FIG. 1

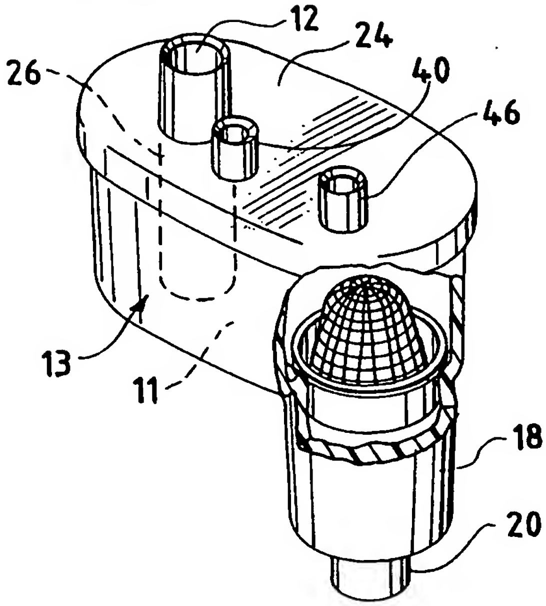


FIG. 2

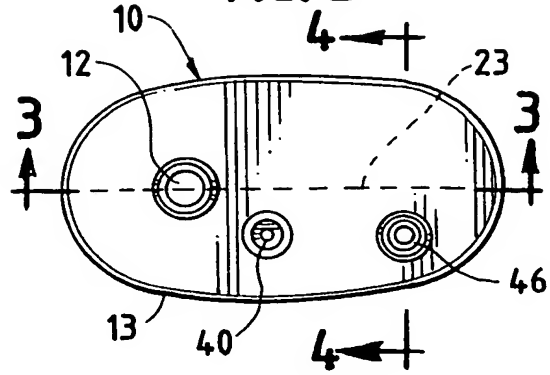


FIG. 3

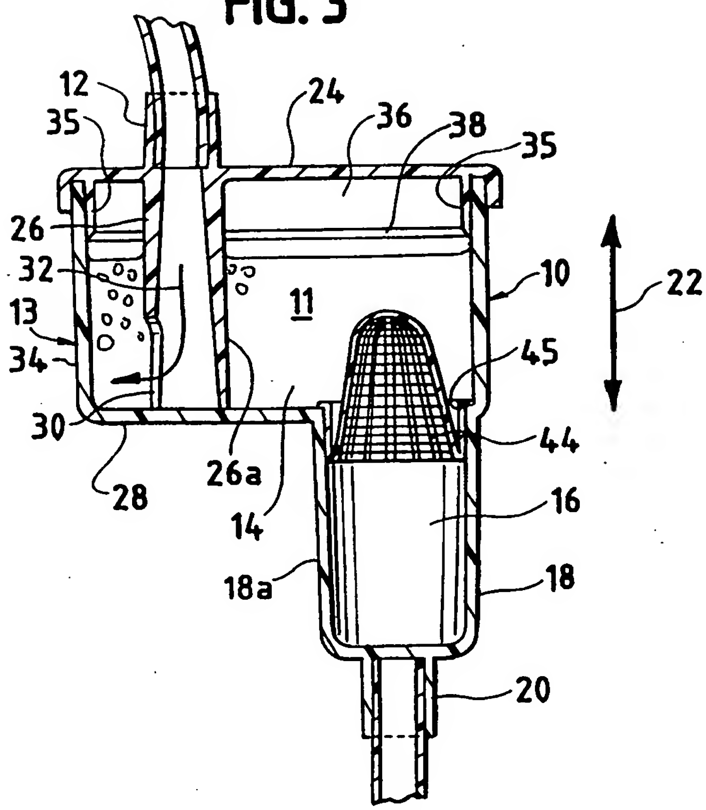


FIG. 4

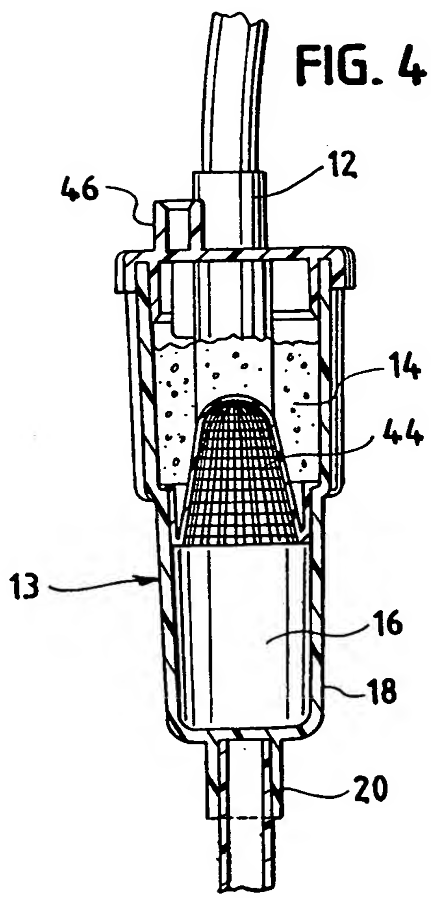


FIG. 5

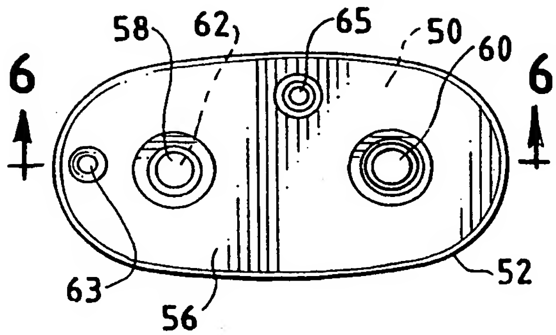


FIG. 6

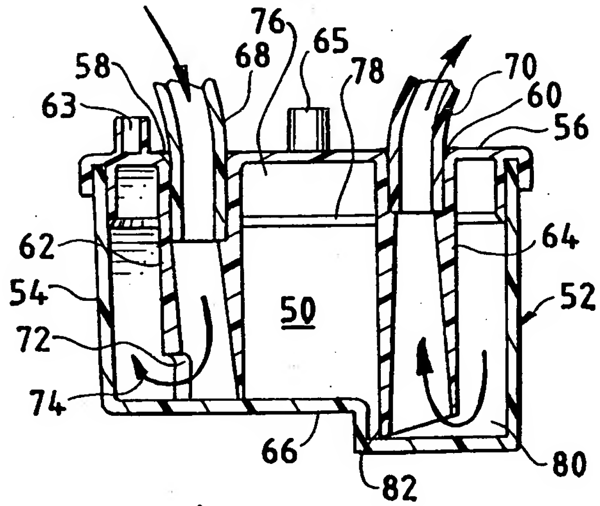


FIG. 7

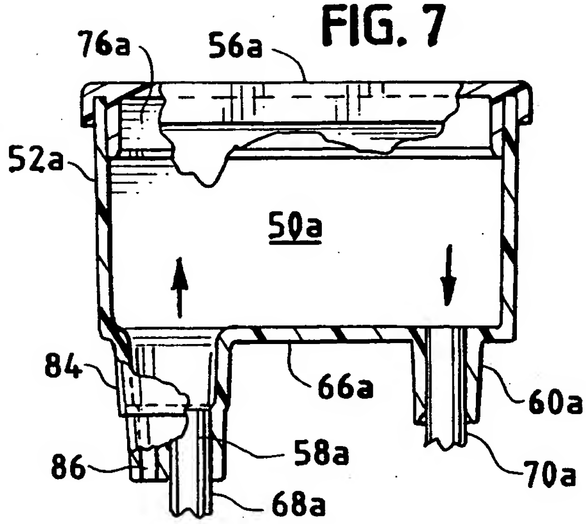


FIG. 8

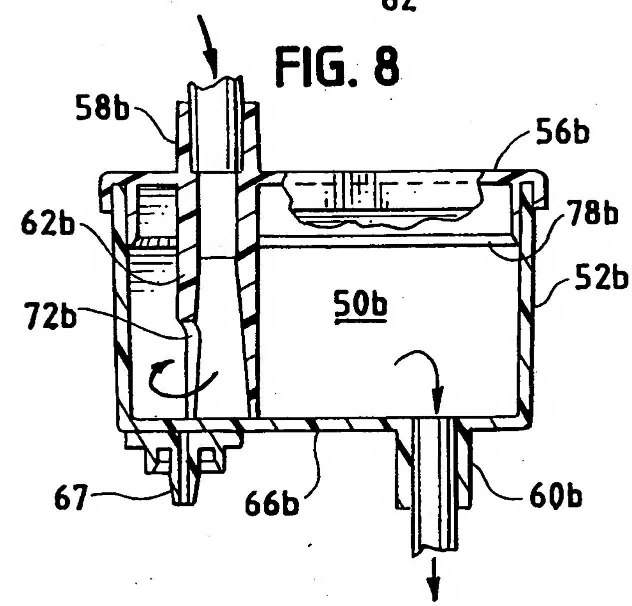


FIG. 9

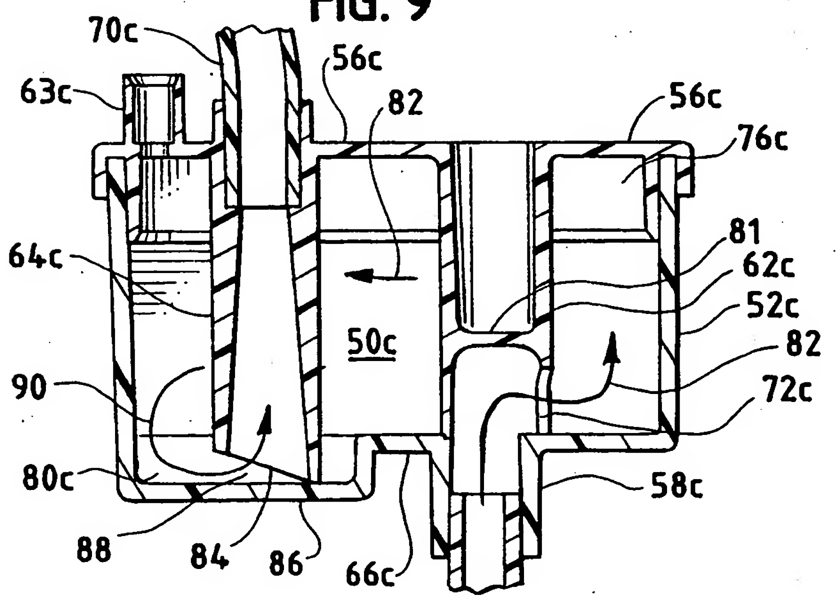


FIG. 10

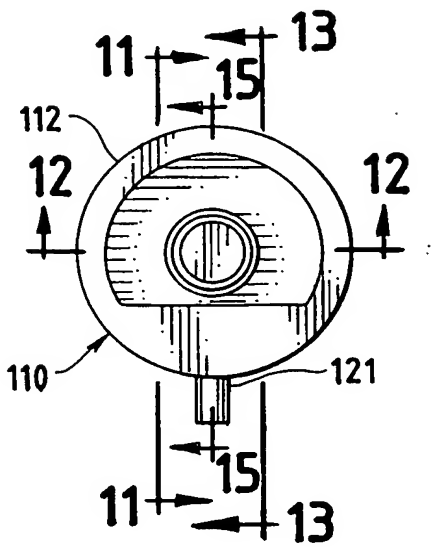


FIG. 11

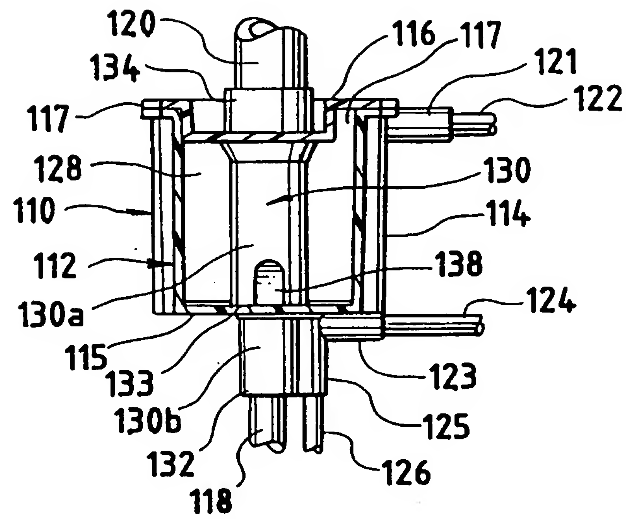


FIG. 12

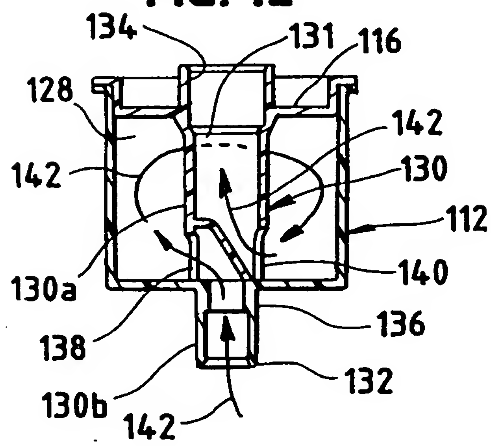


FIG. 13

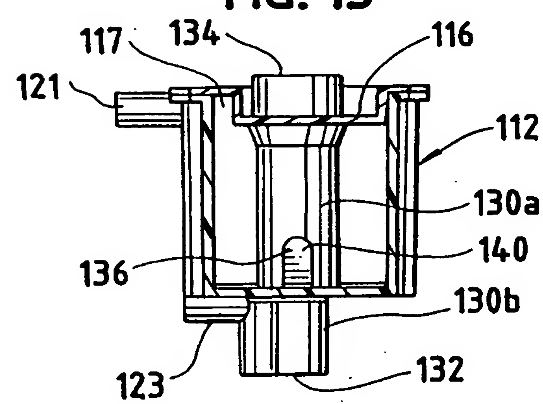


FIG. 14

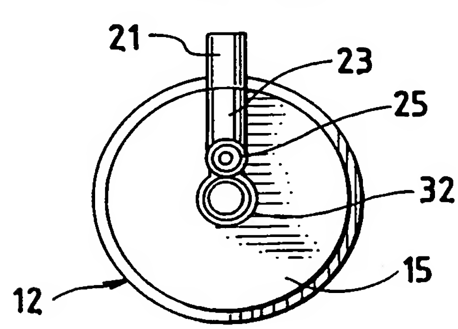


FIG. 15

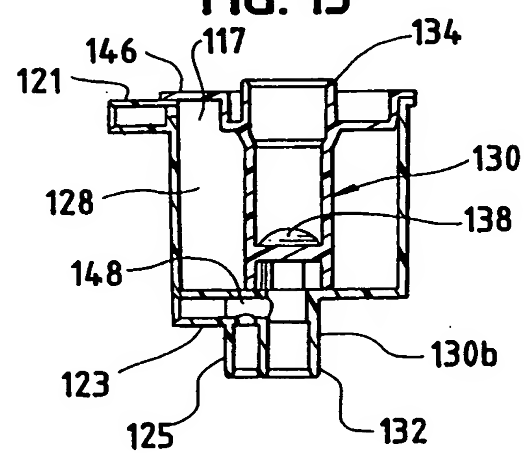


FIG. 16

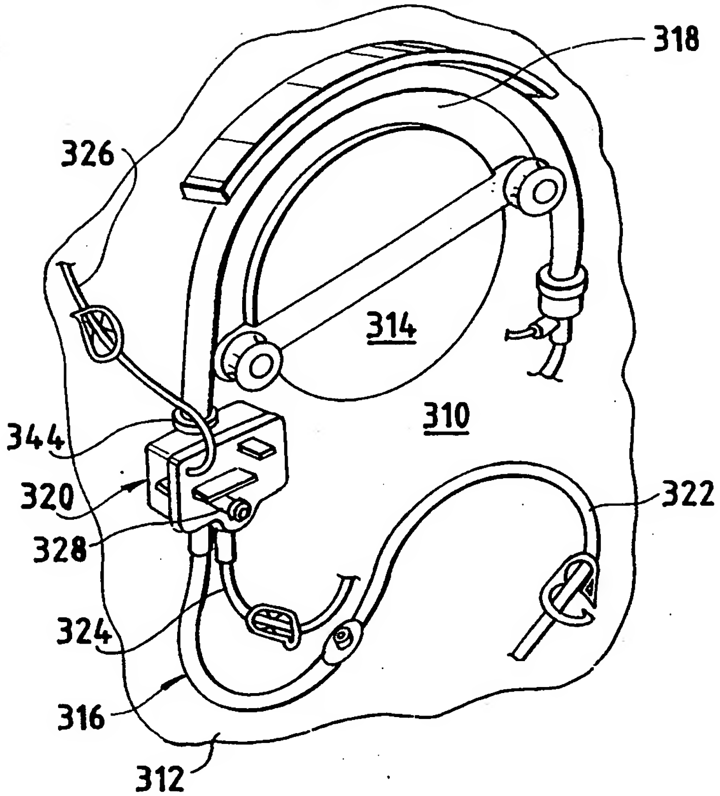


FIG. 18

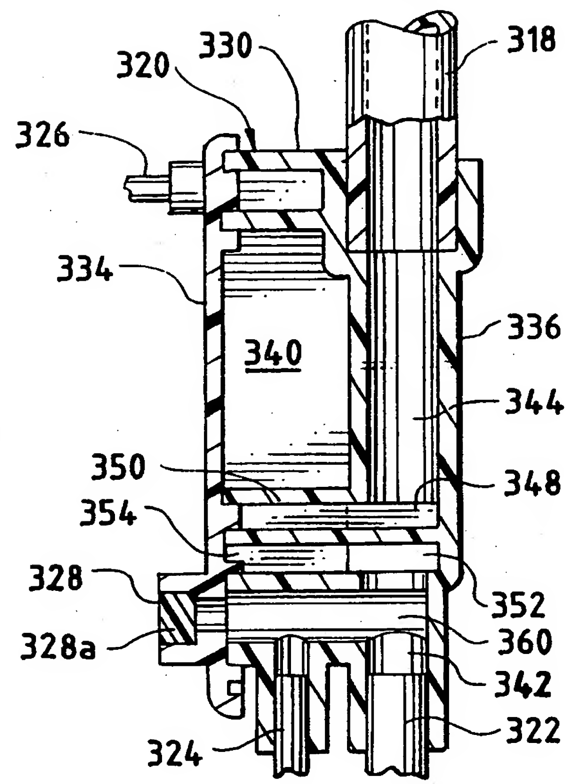


FIG. 17

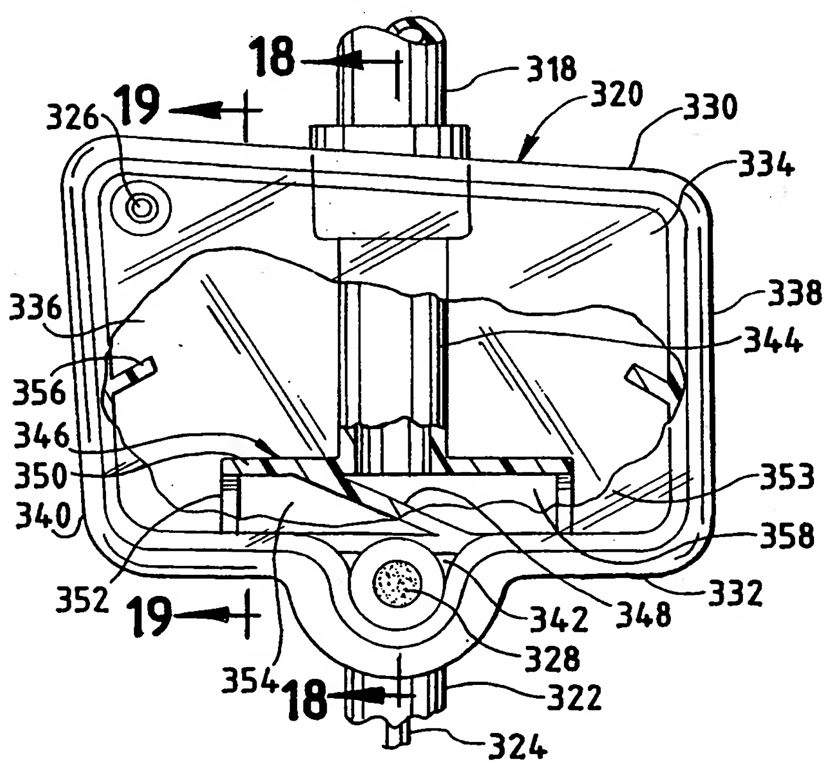


FIG. 19

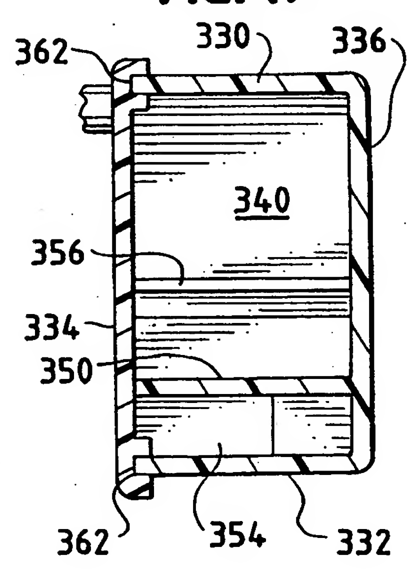


FIG. 20

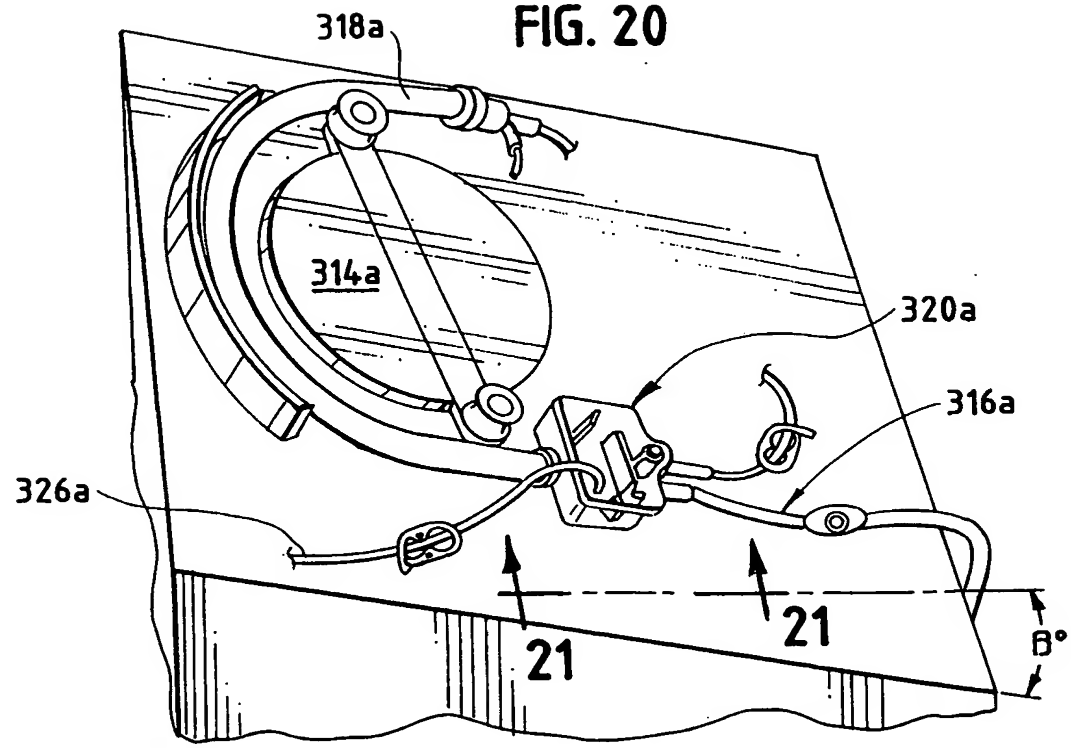


FIG. 21

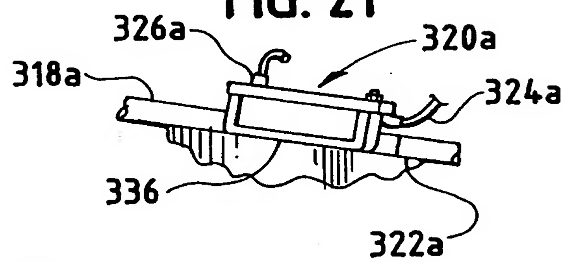
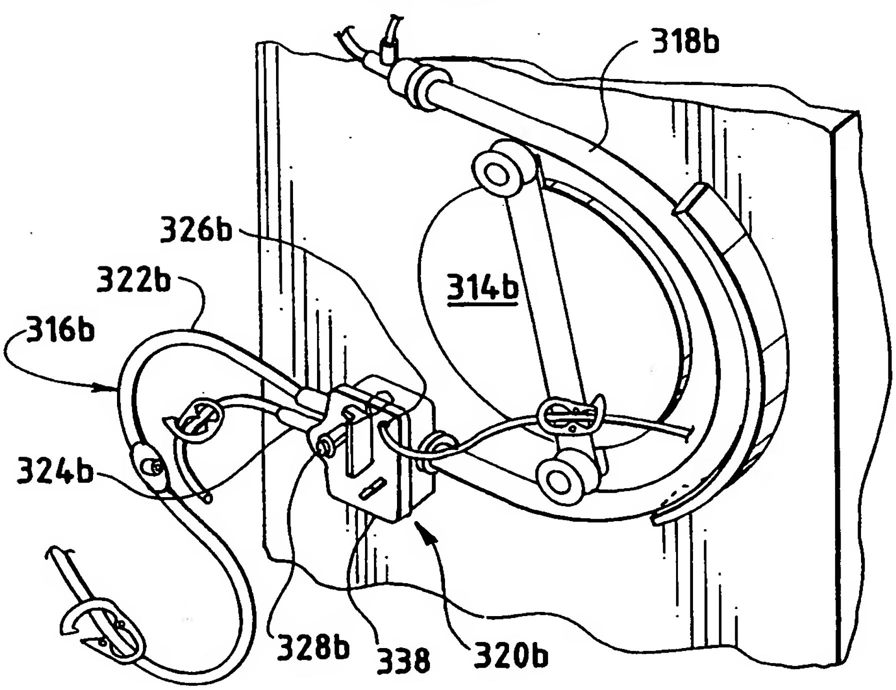


FIG. 22



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21168

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01D 17/12
US CL : 210/95
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/95, 188, 232, 239, 436, 472, 512.1, 519, 539; 422/44-48; 604/4, 122, 123

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,441,636 A (CHEVALLET et al) 15 August 1995, see entire document	44-45
Y	US 5,358,481 A (TODD et al) 25 October 1994, see entire document	29-32 and 36-45
Y	US 5,228,889 A (CORTIAL et al) 20 July 1993, see entire document	1-22 and 33-43
Y	US 5,061,236 A (SUTHERLAND et al) 29 October 1991, see entire document	1-22 and 33-43
Y	US 4,734,269 A (CLARKE et al) 29 March 1988, see entire document	1-43
Y	US 4,722,731 A (VALINCOURT) 02 February 1988, see entire document	23-32

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 FEBRUARY 1998	06 MAR 1998

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	JOSEPH W. DRODGE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0403

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,722,725 A (SAWYER et al) 02 February 1988, see entire document	23-32
Y	US 4,568,333 A (SAWYER et al) 04 February 1986, see entire document	23-32
Y	US 4,531,937 A (YATES) 30 July 1985, see entire document	30-32
Y	US 4,493,705 A (GORDON et al) 15 January 1985, see entire document	1-43
Y	US 4,311,137 A (GERARD) 19 January 1982, see entire document	30-32
Y	US 4,137,160 A (EBLING et al) 30 January 1979, see entire document	44 and 45
Y	US 3,908,653 A (KETTERING) 30 September 1975, see entire document	14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21168

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☒ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet(1))(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21168

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s)1-22 AND 33-43, drawn to a bubble trap constructed so that flow between the ports is primarily horizontal.
Group II, claim(s) 23-32, drawn to a chamber having an inlet/outlet tube that extends across the chamber and having a partition.
Group III, claim(s) 44 and 45, drawn to a flow set for bloodcomprising a central manifold coupled to auxiliary ports and a cannula.

The inventions listed as Groups I, II and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I requires a relatively open chamber and would not contain an inlet/outlet tube extending across the chamber as in Group I or a central manifold as in Group III. The invention of Group II does not require a central manifold as in Group III, while the invention of Group III does not require a partion in an inlet/outlet tube as in Group II.